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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,476	02/20/2002	Gregory D. May	NAPRO-3	4408
7590		01/30/2004	EXAMINER	
Daniel Becker, Esq.		FREDMAN, JEFFREY NORMAN		
FISH & NEAVE		ART UNIT		
1251 Avenue of the Americas		PAPER NUMBER		
New York, NY 10020-1104		1634		

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/082,476

Applicant(s)

MAY ET AL.

Examin r

Jeffrey Fredman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 13-29 in the paper filed November 14, 2003 is acknowledged.

Claim Rejections - 35 USC § 112

2. Claims 13-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what constitutes "recombination and gene repair activities" as claimed in claim 13 since no specific components are required and the terms are not defined by the specification. A careful review of the specification found no definition for either the term "recombination activities" or "gene repair activities". While the term "recombination" has some meaning in the art as involving strand crossover in nucleic acids, there is no clear constraint on what constitutes a "recombination activity". That is, is an enzyme that produces ATP, such as a mitochondrial enzyme, considered a recombination enzyme because without ATP, recombination cannot occur and so the mitochondrial enzyme is essential to the pathway. Alternatively, is a restriction enzyme a "gene repair" enzyme, since it cleaves DNA which is a step that occurs in some gene repair pathways. Given the lack of definition of these terms, and the absence of an ability by the person of skill in the art to define what components fall within the scope of these terms in a definite way, the terms are vague and indefinite.

Claim Interpretation

3. Several of the terms in the claims lack specific definitions and are therefore interpreted in the broadest reasonable way. The term "defined enzyme mixture" is not a defined term, and therefore any mixture of enzymes is deemed to meet this requirement since any mixture is capable of being defined. Similarly, the indefinite terms "recombination and gene repair activities" are deemed to read upon any enzyme that can have activities directly or indirectly involved in these actions.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 13-21, 23-25 and 27-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Cole-Strauss et al (Nucleic Acids Research (1999) 27(5):1323-1330).

Cole-Strauss teaches a composition comprising:

a) a duplex DNA (see page 1324, column 1, subheading "In vitro reaction", where the plasmid DNA is the target DNA).

b) an oligonucleotide (see page 1324, column 1, subheading "oligonucleotides" and "in vitro reaction")

c) a cell free extract (see page 1324, column 1, subheading "cell free extract")

d) a reaction buffer (see column 1, subheading "In vitro reaction" and "cell free extract", where the buffer is a Hepes based buffer).

With regard to claims 14-15, Cole-Strauss teaches an oligonucleotide that is approximately 73 nucleotides in length (see figure 1).

With regard to claim 16, Cole-Strauss teaches an oligonucleotide with a single 3' and 5' end (see figure 1).

With regard to claim 17, Cole-Strauss teaches the Kan gene, which is linked to a promoter that can be expressed (see figure 1).

With regard to claim 18, Cole-Strauss teaches the use of cell extracts deficient in mismatch repair (see page 1327, column 2).

With regard to claim 19, Cole-Strauss teaches the use of mammalian extracts (see page 1324, column 1, subheading "cell free extract").

With regard to claims 20-21, Cole-Strauss teaches an mammalian enzyme mixture (see page 1324, column 1, subheading "cell free extract").

With regard to claims 23-25, 27-28, Cole-Strauss teaches an extract from cells with all of the normal components (see page 1324, column 1, subheading "cell free extract").

With regard to claim 29, Cole-Strauss teaches a self complementary oligonucleotide with at least 5 bases that are base paired (see figure 1).

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6. Claims 13-20, 23-24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamashita et al (EP 718,404 A2, June 1996).

Yamashita teaches a composition comprising:

- a) a duplex DNA (see page 5, table I, here the pUC-Mut solution).
- b) an oligonucleotide (see page 5, table I, here the dR1 solution)
- c) a cell free extract (see page 5, table I, here the RecA protein solution)
- d) a reaction buffer (see page 5, table I, here the 10x reaction buffer).

With regard to claims 14-15, Yamashita teaches an oligonucleotides that are approximately 22-24 nucleotides in length (see SEQ ID Nos: 1-3).

With regard to claim 16, Yamashita teaches an oligonucleotide with a single 3' and 5' end (see SEQ ID NO: 1).

With regard to claim 17, Yamashita teaches the LacZ gene, which is linked to a promoter that can be expressed (see page 4, lines 15-25).

With regard to claim 18, Yamashita teaches the use of solutions deficient in specific mismatch repair enzymes in the prior art (see page 2, lines 10-30).

With regard to claims 19-20, Yamashita teaches the use of the Yeast Rad51 gene product (see page 3, lines 4-15).

With regard to claims 23-24 and 27, Yamashita teaches the use of RecA, which can repair mismatches (see page 5, example 3).

7. Claims 13-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Baszcynski et al (U.S. 6,528,700).

Baszcynski teaches a composition comprising:

- a) a duplex DNA (see column 14, lines 60-65).
- b) an oligonucleotide (see column 14, lines 60-65).
- c) a cell free extract (see column 14, lines 60-65).
- d) a reaction buffer (see column 14, lines 60-65).

With regard to claims 14-15, Baszcynski teaches an oligonucleotide that is approximately 90 nucleotides in length (see SEQ ID NO: 2).

With regard to claim 16, Baszcynski teaches an oligonucleotide with a single 3' and 5' end (see SEQ ID NO: 2).

With regard to claim 17, Baszcynski teaches the double stranded DNA including the pPHPP10247 plasmid which comprises the AHAS gene under the control of the ubiquitin promoter (see column 11, lines 49-67).

With regard to claim 18, Baszcynski teaches the use of cell extracts deficient in mismatch repair (see column 13, line 59, where the heat inactivated WCE would inherently be deficient in mismatch repair activity).

With regard to claims 19-28, Baszcynski teaches the use of plant cell extracts from Maize (see column 13, lines 49-64 and column 14, lines 60-67, subheading "cell free extract" where plant derived mismatch repair and recombination activities are inherently present since the mixture comprises every element of the plant cell).


With regard to claim 29, Baszcynski teaches a self complementary oligonucleotide with at least 5 bases that are base paired (see figure 7).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Jeffrey Fredman
Primary Examiner
Art Unit 1634